UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OFFICE OF THE SECRETARY
2001 MAR 28 A 8 45

BALLOT VOTE SHEET

DATE: March 27, 2001

TO: The Commission
Sadye E. Dunn, Secretary

FROM: Michael S Solender, General Counsel
Stephen Lemberg, Assistant General Counsel
Lowell F. Martin, Attorney-Advisor

SUBJECT: *Federal Register* Notice of Availability of Additional Hydrocarbon Incident Data

Ballot Vote Due: APR 4, 2001

The attached memorandum presents an analysis of additional incident data acquired by CPSC staff after the Commission issued a notice of proposed rulemaking (NPR) to require child-resistant packaging for cosmetics and other household products with viscosity under 100 Saybolt Universal Seconds (SUS) containing 10 percent or more hydrocarbons. 56 Fed Reg. 93 (January 3, 2000).

The Commission may chose to provide an opportunity for public comment on this analysis before considering whether to issue a final rule concerning child-resistant packaging for these products. A draft Federal Register notice that would provide notice of the opportunity for comment is included as Tab C to the attached staff memorandum.

Please indicate your vote on the following options.

I. Provide an opportunity for public comment on the staff analysis of the additional data by issuing the *Federal Register* notice as drafted.

_____ _____
(Signature) (Date)

II. Provide an opportunity for public comment on the staff analysis of the additional data by issuing the draft *Federal Register* notice with changes. (Please specify.)

_____

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_____

_____ _____
(Signature) (Date)

CPSA 6 (b)(1) Cleared
No Mfrs/PrvtLblrs or 3-27-01/NA

NOTE: This document has not been reviewed or accepted by the Commission.
Initial HL Date 3/27/01

III Do not provide an opportunity for public comment on the staff analysis of the additional data

_____

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_____

_____ _____
(Signature) (Date)

IV. Take other action (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: MAR 27 2001

TO : The Commission
Sayde E. Dunn, Secretary

THROUGH : Michael S Solender, General Counsel AR for MSS
Pamela Gilbert, Executive Director PG

FROM : Ronald L Medford, Assistant Executive Director for Hazard Identification and Reduction RLM
Suzanne Barone, Ph D. Project Manager for Poison Prevention, Directorate for Health Sciences SB

SUBJECT : Additional hydrocarbon exposure incident data acquired since the Notice of Proposed Rulemaking

This memorandum presents an overview of the additional incident data that has been obtained by the staff since the Notice of Proposed Rulemaking was published in January 2000.

BACKGROUND

In the Notice of Proposed Rulemaking (NPR) issued by the Commission on January 3, 2000, the Commission proposed child-resistant packaging requirements for household chemical and cosmetic products that contain 10 percent or more hydrocarbons and have a viscosity under 100 SUS at 100°F (65 FR 93). The NPR presented ingestion data for general cosmetic categories that may contain low viscosity hydrocarbons collected by the American Association of Poison Control Centers' (AAPCC) Toxic Exposure Surveillance System (TESS) The categories included creams/lotions/make-up, miscellaneous nail products, bath oil/bubble bath, and suntan/sunscreen products The data presented in the NPR were from the years 1995 through 1997 A total of 74,042 ingestion incidents for these product categories were included While these data were not limited to known hydrocarbon-containing cosmetics, they demonstrate that children access the contents of these types of products in the home. Thus, if the product contains hydrocarbons of low viscosity, aspiration and therefore serious injury could result In addition, the NPR included 1996-1997 AAPCC data for exposures to baby oil, a cosmetic product known to contain low viscosity mineral oil, which is a hydrocarbon

At the Commission decision meeting on December 3, 1999, Commissioner Gall requested that the staff develop a plan for the collection and analysis of additional data

NOTE: This document has not been reviewed or accepted by the Commission.
Initial FH Date 3/27/01

CPSA 6 (b)(1) Cleared
X No Mfrs/Privates or Products Identified 3-27-01 AD

related to ingestion incidents involving mineral oil-based cosmetics [1] In addition, Commissioner Moore requested that the staff seek all available information about products within the scope of the proposed rule [2] The staff recommended, and the Commission approved, the purchase of additional information on ingestion incidents of mineral oil-based cosmetics from the AAPCC Permission was obtained from the AAPCC Board of Directors to purchase brand name data for four cosmetic categories for the year 1998 Data on the following product categories were purchased 1) miscellaneous nail products 2) sunscreen and suntan preparations 3) bubble bath and bath oil 4) creams, lotions, and make-up

A comment was received from the Cosmetic, Toiletry, and Fragrance Association (CTFA) (CP00-1-6) in response to the NPR requesting that they be given the opportunity to review and comment on the additional cosmetic data purchased from the AAPCC. These data contain brand names and must remain proprietary under the terms by which CPSC acquired them from the AAPCC Therefore the database will not be made available to the public However, the staff analysis of the data (Tab A) is available to the public

A summation of data received since the NPR including additional deaths and the special purchase of cosmetic data is presented below

RECLASSIFICATION OF ASPIRATION CASES

Commissioner Gall's specific interest in cases involving mineral oil-based cosmetics prompted a reevaluation by CPSC staff of the data available at the NPR stage with a focus on aspiration The data presented in the NPR contained 114 cases of cosmetic exposure coded as aspirations by the AAPCC for the years 1995, 1996, and 1997 (29, 36, and 49 respectively)

TESS codes identify the routes of exposure for poisoning cases These route codes include, "ingestion," "aspiration," "inhalation/nasal," "ocular," "dermal," "bite/sting," or "parenteral " The 74,042 incidents identified in the NPR were ingestions that did not include other routes of exposure. However, according to AAPCC coding guidelines, all cases coded as aspiration are also coded as ingestions.

Upon reevaluation, the CPSC staff believed that using only incidents coded with the aspiration route of exposure was underestimating the number of aspiration incidents Numerous cases not coded as aspirations resulted in respiratory effects,[3] an indication that aspiration had occurred The CPSC staff

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[1] Statement of the Honorable Mary Sheila Gall on publication of a notice of proposed rulemaking to require special packaging for low-viscosity hydrocarbons, December 3, 1999.
[2] Statement of Commissioner Thomas H Moore on the proposed rule to require child-resistant packaging for low-viscosity hydrocarbons, December 3, 1999.
[3] The AAPCC codes medical effects as being related, unrelated, or unknown if related to the poisoning. CPSC staff analysis only includes cases where the effect is known to be related to the poisoning

then developed a separate set of criteria to identify possible aspiration cases in the AAPCC database

In addition to cases coded as aspirations by the AAPCC, cases with inhalation or nasal routes of exposure as well as ingestion cases with related respiratory effects were considered to be potential aspirations by the CPSC staff Many of these types of cases are not coded as "aspiration" by the AAPCC. For example, a case of aspiration of hydrocarbon following vomiting may not be coded as an aspiration by the AAPCC because the initial route of exposure may have been ingestion However, if these children exhibit respiratory effects related to the poisoning, these cases would be "aspirations" for purposes of this analysis

The CPSC staff reanalyzed the TESS data originally presented in the NPR to take into account the additional cases of potential aspiration In addition, several other changes were made The analysis was expanded to include cases involving all routes of exposure However, cases involving more than one product and cases where the age of the child was unknown were eliminated

The reanalysis of the cosmetic data resulted in 1200 cases of potential aspiration for the years 1995-1997 in comparison with the 114 cases identified by the NPR

The results of the analyses for both cosmetic and chemical product exposures identified in TESS for the years 1993-1999 are presented in Tab B The cosmetic data for the years 1993 through 1999 shows 186,359 exposures with 2,894 potential aspirations Of the 109,823 exposures to household chemicals from product categories that may contain hydrocarbons, 8,221 were potential aspirations.

SUPPLEMENTAL COSMETIC DATA

A more detailed description of the analysis of 1998 cosmetic brand name data is at Tab A.

The special AAPCC cosmetic purchase database contained a total of 31,903 cases coded as miscellaneous nail products; sunscreen and suntan preparations, bubble bath or bath oil, and creams, lotions, and make-up. Of these, 538 cases involved ingestion of more than one substance and were eliminated from consideration Of the 31,365 nonconcomitant ingestions 476 involved potential aspirations as defined by CPSC staff and described above Seventeen of the aspiration cases involved a serious medical outcome.[4] No deaths were reported for these four cosmetic categories during 1998.

[4] Serious medical outcome is defined by CPSC staff as a TESS case with outcome of either moderate effect, major effect, death, or not followed up-potentially toxic.

A total of 2,301 different product codes were involved in the 31,365 incidents However, many cases in the database did not identify the brand name The products were identified by specific category such as baby oil or bath oil

CPSC staff eliminated 2,049 products (22,262 exposures) from further consideration because either the products were known not to contain hydrocarbons or the formulations were emulsions or solids Of the remainder, 30 products (1,461 exposures) would require child-resistant packaging under the proposed rule Staff lacked sufficient information to make that determination for 222 products (7,642 exposures). These products were either from a specific category with some products *that may require packaging under the rule as proposed such as bath oil, or were* products for which no formulation information was available

The staff evaluated the combined cases that were either known to be or might be subject to the rule as proposed The two parameters evaluated were potential aspiration and serious injury As shown in Table 6 of Tab A, a total of five potential aspiration cases were identified as having serious outcomes Three of these cases involved baby oil and two involved bath oil. There were 224 additional cases coded as potential aspirations that did not result in serious effects Seventy-nine cases resulted in serious outcome but did not meet the staff criteria for potential aspiration

The analysis of the 1998 brand name cosmetic data do not alter the conclusions presented in the NPR that children have access to the contents of cosmetic products, and can aspirate cosmetics that contain low-viscosity hydrocarbons with serious medical consequences

ADDITIONAL DEATHS

Tab B contains a discussion of seven fatalities identified in categories of products known to contain hydrocarbons Five of these deaths were not reported in the ANPR or NPR Of these, three deaths were identified in TESS and were caused by products that appear not to be subject to the rule because of the content or the viscosity of the product The first case was the death of a child following ingestions and aspiration of a homemade cleaning product The second case was the death of a child following the ingestion and aspiration of motor oil The final TESS case was the death of a child following the ingestion and aspiration of hair oil. Additional details are at Tab B

The other two deaths that were identified in CPSC databases were apparently caused by products that would be subject to the rule as proposed The first death occurred in 1997 when a 12-month female died 45 days following ingestion of baby oil (970902HCC1459) The autopsy revealed that the child died as a result of a left hemothorax due to complications from swallowing and aspirating baby oil

The second death occurred in 2000 when a 9-month old female died six days following the ingestion of a hair moisturizer product (000824HEP9008). The patient suffered respiratory arrest and died in the intensive care unit

COMMISSION OPTIONS

- Publish the additional information in the Federal Register (FR) for public comment. A draft FR notice to accomplish this is at Tab C.

- Do not publish the additional information in the Federal Register for public comment.

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: MAR 16 2001

TO: Suzanne Barone, Ph D., Pharmacologist
Directorate for Health Sciences

Through: Susan Ahmed, Ph.D., Associate Executive Director
Directorate for Epidemiology

Russell Roegner, Ph D., Director
Division of Hazard Analysis

FROM: C. Craig Morris, Ph.D , Mathematical Statistician
Division of Hazard Analysis

SUBJECT: Pediatric Potential Aspirations of Cosmetic Products: 1998 Data

Per your request, attached is a report on pediatric potential aspiration exposures to cosmetic products during calendar year 1998. Cosmetic exposure data, including brand name information where available, were obtained from the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS).

TAB A

[redacted]

Pediatric Potential Aspirations of Cosmetic Products: 1998 Data

[redacted]

March 2001

C. Craig Morris, Ph.D.
U.S. Consumer Product Safety Commission
Directorate for Epidemiology
Division of Hazard Analysis
4330 East West Highway
Bethesda, MD 20814

Executive Summary

This report documents a high incidence of pediatric exposure to cosmetic products frequently containing hydrocarbon compounds known to pose an aspiration hazard to young children. Data were obtained from the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) for calendar year 1998. Results were as follows:

- A total of 31,365 exposures of children under 5 years old to cosmetic products without concomitant exposure to other products were reported to TESS in 1998. An additional 538 exposures to cosmetic products involved concomitant exposure to other products.

- Of the 31,365 nonconcomitant pediatric exposures, 476 involved *potential aspiration,* defined as a reported nasal/inhalation or aspiration route of exposure or an ingestion with related respiratory effects.

- Of the 476 potential aspirations, 245 resulted in a minor medical outcome, 12 in a moderate medical outcome, 2 in a major medical outcome, and 3 in a potentially toxic outcome which could not be followed up.

- Potential aspiration victims were typically under 3 years old (88%), although some incidents involved 3- and 4-year olds (12%).

- The most frequently reported respiratory effect was coughing/choking (74%), but bronchospasm, dyspnea, pneumonitis, hyperventilation/tachypnea, and positive X-ray findings were also reported.

- Brand or generic names of cosmetic products involved in potential aspirations and serious medical outcomes were determined where available. The 31,365 nonconcomitant pediatric exposures to cosmetics reported to TESS in 1998 involved a total of 2,301 brand/generic names. Staff determined that 2,049 of these brand/generic name products would *not* be affected by the draft regulation, 30 would be affected, and 222 might or might not be affected (i.e., staff lacked sufficient information about the latter products to make a determination).

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Pediatric Potential Aspirations of Cosmetic Products: 1998 Data

Certain cosmetic products frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. This report describes potential aspirations of cosmetic products by children under 5 years old during calendar year 1998 and is one of several recent U.S. Consumer Product Safety Commission (CPSC) reports and memoranda on hydrocarbon-related pediatric poisonings [1-7]. Data are from the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS).

Method

The AAPCC TESS compiles data on reported poisoning incidents in the United States [8]. TESS data are based on follow-up investigations of telephone calls reporting poisoning exposures to poison control centers. Most certified poison control centers in the U.S. participate in TESS, but the number of participating centers fluctuates annually. Because TESS is not a probability sample of poison control centers, TESS cannot provide national estimates, but TESS data are the most comprehensive data available on pediatric toxic exposures in the U.S CPSC purchases TESS data for victims under 5 years old annually. To identify specific products involved in pediatric cosmetic aspirations, the U S. Consumer Product Safety Commission (CPSC) purchased a special data set containing brand name information along with the exposure and medical information for pediatric cosmetic exposure cases reported to TESS during 1998.

This report presents TESS data on *acute, general unintentional* exposures involving children under 5 years old. TESS defines an *acute* exposure as a single or repeated exposure occurring over a period of no more than eight hours TESS defines a *general unintentional* exposure as an unintentional exposure that does not involve environmental or occupational exposure, therapeutic error, misuse of the product, bite/sting, food poisoning, or an unknown source of exposure. **Appendix A** gives TESS definitions of *exposure routes, medical outcomes,* and *respiratory clinical effects.*

TESS defines an *aspiration* as an exposure by the pulmonary (tracheal) route that is usually associated with the ingestion of liquid or solid agents. TESS automatically codes an aspiration exposure as an ingestion exposure. This report defines a *potential aspiration* exposure as a case for which the TESS record indicates either aspiration, ingestion with related respiratory effects, or nasal/inhalation exposure [6]. TESS specifies the *medical outcome* of each reported exposure, including several *not followed up* categories. This report defines a *serious medical outcome* as a case for which the TESS record indicates a medical outcome of either *moderate effect, major effect, death,* or *not followed up-potentially toxic.*

TESS generic codes capture groups of similar substances involved in toxic exposures. This report presents data for certain substances, referred to in the present report as *cosmetics,* that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. These substances are found in the TESS groups (generic codes): *bath oil/bubble bath* (077329), *creams/lotions/makeup* (077322), *nail products/miscellaneous* (077325), *suntan/sunscreen products* (077345).

Results

During calendar year 1998, TESS reported 31,903 pediatric cosmetic exposures meeting the criteria described above. **Table 1** gives the data. Of the 31,903 exposures, 538 involved concomitant exposure to more than 1 product and are not considered further in this report. Of the 31,365 cases without concomitant exposure to any other product, 17 involved potential aspiration *with* a serious medical outcome, 459 involved potential aspiration *without* a serious medical outcome, 248 involved a serious medical outcome *without* potential aspiration, and 30,641 involved *neither* potential aspiration *nor* a serious medical outcome. Of the 476 potential aspirations, 247 involved *bath oil/bubble bath* (TESS code 077329), 160 involved *creams/lotions/makeup* (077322), 41 involved *nail products/miscellaneous* (077325), and 28 involved *suntan/sunscreen products* (077345).

Table 1. *Exposures of Children under 5 Years Old to Cosmetic Products Reported to TESS in 1998*

Total cosmetic exposures *without* concomitants	31,365
Potential aspiration *with* serious medical outcome	17
Potential aspiration *without* serious medical outcome	459
Serious medical outcome *without* potential aspiration	248
Neither potential aspiration *nor* serious medical outcome	30,641
Total cosmetic exposures *with* concomitants	538
Total cosmetic exposures	31,903

Source. American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

Medical Outcome

Of the 476 nonconcomitant potential aspiration exposures, 17 involved a *serious medical outcome* as described above. TESS indicated that 32 cases resulted in *no* medical outcome, 245 in a *minor* outcome, 12 in a *moderate* outcome, 2 in a *major* outcome, and 3 were *potentially toxic* but not followed up. TESS also indicated that 159 cases with a minor outcome were not followed up, 18 were nontoxic and not followed up, and 5 involved unrelated medical effects. None of the 476 potential aspirations resulted in fatality.

Respiratory Effects

Table 2 gives nonconcomitant pediatric cosmetic potential aspiration cases by related respiratory clinical effect (see definitions in **Appendix A**). The most frequently reported respiratory effect was coughing/choking. Other reported respiratory effects included bronchospasm, dyspnea, pneumonitis, hyperventilation/tachypnea, and positive X-ray findings.

Table 2. *Nonconcomitant Cosmetic Potential Aspirations Reported to TESS for Children under 5 Years Old in 1998 by Respiratory Effect in 1998*

Respiratory Effect	Frequency
None	116
Bronchospasm	1
Cough/Choke	351
Dyspnea	2
Bronchospasm, Cough/Choke	1
Cough/Choke, Dyspnea	3
Cough/Choke, Hyperventilation/Tachypnea, Pneumonitis	1
Hyperventilation/Tachypnea, Positive X-ray Findings	1
Total	476

Source: American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission. Note: The last 4 rows indicate multiple effects.

Age and Gender

Table 3 gives nonconcomitant cosmetic potential aspirations by age and gender for children under 5 years old in 1998. The majority of these potential aspirations (88.2%) involved children under 3 years old, with males (50.8%) and females (49.2%) almost equally represented.

Table 3. *Nonconcomitant Cosmetic Potential Aspirations Reported to TESS for Children under 5 Years Old in 1998 by Age and Gender*

Age (Years)	Male	Female	Total
< 1	33	34	67
1	114	124	238
2	61	53	114
3	21	15	36
4	13	8	21
Total	242	234	476

Source. American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

Exposure Patterns

Table 4 gives the frequencies of observed exposure patterns for the 31,365 nonconcomitant pediatric cosmetic poisoning exposures. Of the 476 potential aspiration cases, there were 337 cases of ingestion with related respiratory effects, 9 cases of nasal exposure with related respiratory effects, and 2 cases of nasal and ingestion exposure with related respiratory effects, that TESS did not code as aspirations. In addition, there were 50 cases of nasal exposure without respiratory effects, and 26 cases of nasal and ingestion exposure without respiratory effects, that TESS did not code as aspirations. Finally, TESS did code as aspirations 12 cases of ingestion with related respiratory effects and 40 cases of ingestion with *no* related respiratory effects.

The majority of the remaining nonconcomitant pediatric cosmetic exposures involved either ingestion with no reported respiratory effects (n = 27,908) or various other exposure routes such as ocular or dermal (n = 2,981). See **Appendix A** for exposure route definitions.

Table 4. *Nonconcomitant Pediatric Cosmetic Potential Aspiration Exposure Patterns involving Children under 5 Years Old in 1998*

Exposure Pattern	Frequency
Potential Aspiration	
-N -A +I +R	337
-N +A +I +R	12
-N +A +I -R	40
+N -A +I +R	2
+N -A -I -R	50
+N -A -I +R	9
+N -A +I -R	26
Other Exposure	
-N -A +I -R	27,908
-N -A -I +R	1
-N -A -I -R	2,980
Total	31,365

Source: American Association of Poison Control Centers TESS file and U.S Consumer Product Safety Commission. Note: N, A, I, R denote nasal exposure, coded aspiration, ingestion exposure, and respiratory effects; + or - denote presence or absence of the given route or effect.

Cosmetic Products by Brand/Generic Name

To assess any possible association of brand/generic (B/G) name information with potential aspiration and/or serious medical outcome, CPSC staff classified each of the 31,365 nonconcomitant pediatric exposures into one and only one of four mutually exclusive and exhaustive groups: potential aspiration *with* serious medical outcome (+P+S), potential aspiration *without* serious medical outcome (+P-S), serious medical outcome *without* potential aspiration (-P+S), and *neither* serious medical outcome *nor* potential aspiration (-P-S). As already shown in Table 1, this analysis revealed 17 cases in the +P+S group, 459 cases in the +P-S group, 248 cases in the -P+S group, and 30,641 cases in the -P-S group. The analysis also revealed 2,301 different B/G names involved in the 31,365 nonconcomitant exposure cases. CPSC Health Sciences staff classified each of the 2,301 different B/G names by whether that product *would*, *might* (insufficient information to make a firm determination), or *would not* be affected by the draft regulation [7].

Table 5 gives the number of different B/G name products and exposure cases associated with each of these 3 categories with respect to the draft regulation, i.e., possibly in-scope (*might* be affected by the draft regulation), in-scope (*would* be affected), and out-of-scope (*would not* be affected). As shown in Table 5, there were 7,642 exposures associated with 222 B/G name products that *might* be affected, 1,461 exposures associated with 30 B/G name products that *would* be affected, and 22,262 exposures associated with 2,049 B/G names that *would not* be affected by the draft regulation.

Table 5. *Number of Reported Exposures (Brand/Generic Names) by Potential Aspiration/Serious Outcome Group and Brand/Generic Name Classification*

	Number of B/G Names	Number of Exposures
B/G name possibly in-scope	222	7,642
B/G name in-scope	30	1,461
B/G name out-of-scope	2,049	22,262
Total	2,301	31,365

Note: B/G denotes Brand/Generic, +P+S denotes potential aspiration *with* serious medical outcome, +P-S denotes potential aspiration *without* serious medical outcome, and -P+S denotes serious medical outcome *without* potential aspiration. Source: American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

Table 6 gives the breakdown of the 308 in-scope or possibly in-scope exposure cases involving either potential aspiration, serious medical outcome, or both, by potential aspiration/serious outcome group and B/G name classification with respect to the draft regulation; each number in parentheses is the number of different B/G names associated with the number of injuries to the left of that number in the table. Note that a given B/G name can appear in more than one of the potential aspiration/serious outcome groups.

Table 6. *Number of Reported Exposures (Brand/Generic Names) by Potential Aspiration/Serious Outcome Group and Brand/Generic Name Classification*

	+P+S		+P-S		-P+S	
B/G name possibly in-scope	2	(1)	169	(30)	72	(20)
B/G name in-scope	3	(2)	55	(5)	7	(4)
Total	5	(3)	224	(35)	79	(24)

Note: B/G denotes Brand/Generic, +P+S denotes potential aspiration *with* serious medical outcome, +P-S denotes potential aspiration *without* serious medical outcome, and -P+S denotes serious medical outcome *without* potential aspiration. Source: American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

Conclusion

This report documents a high incidence of pediatric exposure to a product group (cosmetics) that frequently contains hydrocarbon compounds known to pose an aspiration hazard to young children. Data were obtained from the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) for calendar year 1998. Results were as follows. A total of 31,365 exposures of children under 5 years old to cosmetics without concomitant exposure to other products were reported to TESS in 1998. An additional 538 exposures to cosmetic products occurred but involved concomitant exposure to other products. Of the 31,365 nonconcomitant pediatric exposures, 476 involved *potential aspiration,* defined as a reported nasal/inhalation or aspiration route of exposure or an ingestion with related respiratory effects. Of the 476 potential aspirations, 245 resulted in a minor medical outcome, 12 in a moderate medical outcome, 2 in a major medical outcome, and 3 in a potentially toxic outcome which could not be followed up. The victims of pediatric potential aspirations were typically under 3 years old (88%), although some incidents involved 3- and 4-year olds (12%). The most frequently reported respiratory effect was coughing/choking (74%), but bronchospasm, dyspnea, pneumonitis, hyperventilation/tachypnea, and positive X-ray findings were also reported. Specific brand names of cosmetic products involved in ingestions, potential aspirations, and serious medical outcomes were analyzed where available to assess whether those products would be affected by the draft child-resistant packaging regulation for certain hydrocarbon products. The 31,365 acute, unintentional nonconcomitant pediatric exposures to cosmetics reported to TESS in 1998 involved a total of 2,301 brand/generic names. CPSC Health Sciences staff determined that 2,049 of these brand/generic name products would *not* be affected by the draft regulation, 30 would be affected, and 222 might or might not be affected (i e., Health Sciences staff lacked sufficient information about the latter group to make a firm determination).

References

1. Boudreault MA, Singh H. *Petroleum distillates and pine oil products*. Washington, DC: U.S. Consumer Product Safety Commission; 1997.

2. Morris, CC. *Pediatric baby oil exposure incidents*. Washington, DC: U.S. Consumer Product Safety Commission; 1998.

3. Morris, CC. *Pediatric hydrocarbon ingestions and aspirations*. Washington, DC: U.S. Consumer Product Safety Commission; 1999.

4. Morris, CC. *Pediatric baby oil potential aspirations*. Washington, DC: U.S. Consumer Product Safety Commission, 2000.

5. Morris, CC. *Pediatric hydrocarbon ingestions and potential aspirations*. Washington, DC: U.S. Consumer Product Safety Commission; 2000.

6. Barone S. *Classification of hydrocarbon-based product poisonings as "potential aspirations."* Memorandum from Suzanne Barone to C. Craig Morris Washington, DC: U.S. Consumer Product Safety Commission; 2000.

7. Barone, S. *Elimination of out-of-scope cosmetic cases from the brand name data obtained from the American Association of Poison Control Centers (AAPCC)* Memorandum from Suzanne Barone to C. Craig Morris. Washington, DC: U.S Consumer Product Safety Commission; 2000.

8. Litovitz TL, Klein-Schwartz W, Caravati EM, Youniss J, Crouch B, Lee S. 1998 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. *Am J Emerg Med*. 1998;17(5):435-487.

Appendix A

Definitions of TESS *Exposure Routes*, *Medical Outcomes*, and *Respiratory Clinical Effects*

Exposure Routes

Ingestion: An exposure by the oral route. Exposures in which the material was put in the mouth but unlikely to have reached the stomach should be classified as ingestions. Ingestions accompanied by aspiration should be coded as aspirations. If aspiration is coded, ingestion will automatically be coded. It is not an error to code both ingestion and aspiration.

Inhalation/nasal: An exposure by the pulmonary route (tracheal or nasal). This route usually pertains to gaseous or vaporized agents.

Aspiration: An exposure by the pulmonary route (tracheal). This route usually pertains to liquid or solid agents and occurs during or following an ingestion. If aspiration is coded, ingestion will automatically be coded by the scanner or your on-line system It is not an error to code both ingestion and aspiration.

Ocular: An exposure involving the eyeball.

Dermal: An exposure involving the skin, hair, or fingernails.

Bite/sting: An exposure resulting from an animal bite or sting with or without envenomation.

Parenteral: An exposure resulting from the injection of a substance into the body.

Other: Any other route of exposure not listed above.

Unknown: The route of exposure is unknown.

Note: At least one route must be selected. Multiple routes may be selected.

Medical Outcomes

No Effect: The patient developed no signs or symptoms as a result of the exposure.

Minor Effect: The patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved rapidly without residual disability or disfigurement.

Moderate Effect: The patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms. Symptoms were not life-threatening, and the patient has no residual disability. Usually some form of treatment is indicated.

Major Effect: The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement, e.g , repeated seizures or status epilepticus, respiratory compromise requiring intubation, ventricular tachycardia with hypotension.

Death: Only those deaths which are probably or undoubtedly related to the exposure are coded here.

Unrelated Effect: The exposure was probably not responsible for the clinical effect.

No Follow Up: Either the patient could not be followed in spite of a potentially significant exposure or follow-up calls were limited because the substance implicated was nontoxic, the amount was insignificant, or the exposure was likely to result in only minimal toxicity.

Respiratory Clinical Effects

Bronchospasm: Narrowing of bronchi by muscular contraction in response to some stimulus; wheezing; reactive airway diseases.

Cough/Choke: A form of violent exhalation by which irritant particles in the airways can be expelled; interruption of respiration by obstruction.

Cyanosis: Bluish discoloration of the skin and mucuous membranes.

Dyspnea: Labored or difficult breathing; shortness of breath.

Hyperventilation/Tachypnea: Breathing at an abnormally rapid rate at rest; diagnosis is usually made with an arterial blood gas.

Pneumonitis: Inflammation of the pulmonary parenchyma.

Pulmonary edema: Accumulation of fluid in the lungs. Include cardiogenic and noncardiogenic etiologies.

Respiratory arrest: Cessation of spontaneous respirations.

Respiratory depression: Diminshed tidal volume and/or rate. Inadequate ventilation. Use this code only if objective information is provided to support the diagnosis of respiratory depression.

X-ray findings (+): Pulmonary X-ray findings other than normal.

TAB B

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: FEB 26 2001

TO: Suzanne Barone, Ph.D., Pharmacologist
Directorate for Health Sciences

Through: Susan Ahmed, Ph.D., Associate Executive Director
Directorate for Epidemiology

Russell Roegner, Ph.D., Director
Division of Hazard Analysis

FROM: C. Craig Morris, Ph.D., Mathematical Statistician
Division of Hazard Analyis

SUBJECT: Pediatric Hydrocarbon Exposures and Potential Aspirations

Per your request, attached is a report on pediatric hydrocarbon-related injuries during calendar years 1993 through 1999. Data sources include the U.S. Consumer Product Safety Commission (CPSC) National Electronic Injury Surveillance System (NEISS) and the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS).

Pediatric Hydrocarbon Exposures and Potential Aspirations

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Executive Summary

This report documents a high incidence of pediatric exposure to certain cosmetics and household chemical product groups that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. Data sources include the U.S. Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) and In-Depth Investigations (INDP) files and the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) file.

CPSC NEISS Data

- NEISS data for 1997 through 1999 yielded an estimated total number of pediatric exposures involving household chemicals of about 6,400. NEISS household chemical data are not directly comparable to TESS data, because NEISS product code categories do not correspond to TESS generic code categories. NEISS does not currently distinguish different cosmetic products, so cosmetic-related injuries reported to NEISS are not included in this report.

AAPCC TESS Data

- From 1993 through 1999, there were 296,182 pediatric hydrocarbon exposures, with 186,359 related to *cosmetics*, and 109,823 related to *household chemicals*. During the same period, there were 11,115 reported *potential aspiration* exposures, with 2,894 related to *cosmetics*, and 8,221 related to *household chemicals*.

- Children under 3 years old were involved in 88.4% of *cosmetic* exposures and 83.8% of *household chemical* exposures.

- Males (females) were involved in 50.8% (49.0%) of *cosmetic* exposures and 58.9% (40.8%) of *household chemical* exposures. Gender was unknown in 0.2% of cases.

- Of the 11,115 potential aspirations in the combined *cosmetics* and *household chemicals* data, 1,108 resulted in a moderate medical outcome, 73 resulted in a major medical outcome, and 3 resulted in death. Aspiration of a hydrocarbon product classified in another TESS category [*hair care products, other (excluding peroxide)*] resulted in a fourth aspiration-related fatality.

- *Related respiratory effects* were associated with potential aspiration of these products. The related respiratory effects included 8,039 cases of coughing/choking, 511 cases of positive X-ray findings, 402 cases of dyspnea, 214 cases of hyperventilation/tachypnea, 190 cases of pneumonitis, 80 cases of bronchospasm, 44 cases of respiratory depression, 38 cases of cyanosis, 12 cases of respiratory arrest, and 8 cases of pulmonary edema.

AAPCC TESS and CPSC INDP Fatality Data

- Of 4 aspiration-related pediatric fatalities reported in TESS from 1993 through 1999, at least 1 and possibly 3 involved pertinent hydrocarbon products. CPSC INDP data revealed an additional 3 fatalities pertinent to this class of hydrocarbons.

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Pediatric Hydrocarbon Exposures and Potential Aspirations

This report describes pediatric hydrocarbon exposures and potential aspirations reported in the U.S. Previous reports presented related analyses for calendar years 1990 through 1994 [1] and 1995 through 1997 [2]. This report presents data for 1997 through 1999 from the U.S. Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) and In-Depth Investigations (INDP) files and for 1993 through 1999 from the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) file.

CPSC NEISS Hydrocarbon Exposure Data

Method

The NEISS collects data on hospital emergency room-treated injuries via a probability sample of hospitals in the United States and its territories [3,4]. This report presents NEISS data on products that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. NEISS selection criteria were: *product codes* 833 (workshop compounds or chemicals), 909 (adhesives, excluding tapes), 913 (lubricants), 931 (metal polishes, tarnish removers, or preventatives), 955 (automotive chemicals, excluding antifreeze, lubricants, waxes, and windshield wiper fluids), 960 (paints, varnishes, or shellacs), 977 (spot removers or cleaning fluids), 978 (automotive waxes, polishes, or cleaners); *diagnosis* 68 (poisoning); *body part* 85 (all parts of body, more than 50% of body); *age* under 5 years old, and *treatment date* 1 Jan 1997 through 31 Dec 1999.

Estimated Injuries

Table 1 gives estimated hydrocarbon-exposure injuries to children under 5 years old by product group for 1997 through 1999.

Table 1. *Estimated Hydrocarbon-Exposure Injuries to Children under 5 Years Old for 1997 through 1999*

Product Group	Code	Estimated Injuries	CV
Workshop compounds or chemicals	833	0	----
Adhesives, excluding tapes	909	1,215	0.188
Lubricants	913	834	0.277
Metal polishes, tarnish removers, or preventatives	931	259	0.468
Selected automotive chemicals	955	885	0.241
Paints, varnishes, or shellacs	960	1,988	0.316
Spot removers or cleaning fluids	977	725	0.327
Automotive waxes, polishes, or cleaners	978	506	0.331
Total		6,412	

Source: U.S. Consumer Product Safety Commission NEISS file, 12 October 2000.
Note: CV = coefficient of variation.

AAPCC TESS Hydrocarbon Exposure and Potential Aspiration Data

Method

The AAPCC TESS compiles data on reported poisoning incidents in the United States [5]. TESS data are based on follow-up investigations of telephone calls reporting poisoning exposures to poison control centers. Most certified poison control centers in the U.S. participate in TESS, but the number of participating centers fluctuates annually. Because TESS is not a probability sample of poison control centers, TESS cannot provide national estimates, but TESS data are the most comprehensive data available on pediatric toxic exposures in the U.S. CPSC purchases TESS data for victims under 5 years old annually.

This report presents TESS data on *acute*, *general unintentional* exposures to a single substance, without concomitant exposure to other substances, involving children under 5 years old. TESS defines an *acute* exposure as a single or repeated exposure occurring over a period of no more than eight hours. TESS defines a *general unintentional* exposure as an unintentional exposure that does not involve environmental or occupational exposure, therapeutic error, misuse of the product, bite/sting, food poisoning, or an unknown source of exposure. **Appendix A** gives TESS definitions of *exposure routes*, *medical outcomes*, and *respiratory clinical effects*.

Previous CPSC reports [1,2] gave data on pediatric *ingestion* exposures some of which involved concomitant exposures to more than one product and included a few cases where age was coded *unknown age-child*. In contrast, the present report gives data on *all* in-scope pediatric exposures (*i.e.*, ingestion, aspiration, nasal/inhalation, etc.) that did *not* involve concomitant exposure to more than one product and excludes any cases where age was unknown.

TESS defines an *aspiration* as an exposure by the pulmonary (tracheal) route that is usually associated with the ingestion of liquid or solid agents. TESS automatically codes an aspiration exposure as an ingestion exposure. This report defines a *potential aspiration* exposure as a case for which the TESS record indicates either aspiration, ingestion with related respiratory effects, or nasal/inhalation exposure [6,7]. TESS specifies the *medical outcome* of each reported exposure, including several *not followed up* categories. This report defines a *serious medical outcome* as a case for which the TESS record indicates a medical outcome of either *moderate effect*, *major effect*, *death*, or *not followed up-potentially toxic*.

This report presents data for 2 classes of substances, referred to in the present report as *cosmetics and household chemicals*, that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. The *cosmetics* class includes the groups (generic codes): creams/lotions/makeup (077322), nail products/miscellaneous (077325), bath oil/bubble bath (077329), suntan/sunscreen products (077345). The *household chemicals* class includes the groups (TESS generic codes): carpet/upholstery/leather/vinyl cleaner (013290), automotive hydrocarbons (039220), spot remover/dry cleaning – hydrocarbon (039281), lubricating oil/motor oil (039505), hydrocarbon – other (039510), hydrocarbon – unknown (039511), rust remover/other/unknown (077307), floor wax/polish/sealer (077586), toluene/xylene - adhesive only (191103), toluene/xylene – excluding adhesive (191500), stains (254366), varnish/lacquers (254367). In the following, data are presented first for cosmetics, then for household chemicals, and finally for cosmetics and household chemicals combined

Cosmetics Exposures

Age

Table 2 gives cosmetic *potential aspirations* and *other exposures* for children under 5 years old by *age*. There were 186,359 reported exposures from 1993 through 1999, 88.4% of which involved children under 3 years old.

Table 2. *Cosmetic Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Age for 1993 through 1999*

Age	Other Exposures	Potential Aspirations	Total (%)
0-11 Months	27,312	364	27,676 (14.9)
1 Year	81,979	1,384	83,363 (44.7)
2 Years	53,001	737	53,738 (28.8)
3 Years	15,326	284	15,610 (8.4)
4 Years	5,847	125	5,972 (3.2)
Total	183,465	2,894	186,359 (100.0)

Source: American Association of Poison Control Centers TESS file.

Sex

Table 3 gives cosmetic *potential aspirations* and *other exposures* for children under 5 years old by *sex*. Males were involved in both total exposures and potential aspirations slightly more frequently than females.

Table 3. *Cosmetic Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Sex for 1993 through 1999*

Sex	Other Exposures	Potential Aspirations	Total (%)
Male	93,229	1,494	94,723 (50.8)
Female	89,831	1,396	91,227 (49.0)
Unknown	405	4	409 (00.2)
Total	183,465	2,894	186,359 (100.0)

Source: American Association of Poison Control Centers TESS file.

Year

Table 4 gives cosmetic *potential aspirations* and *other exposures* for children under 5 years old by *year* for 1993 through 1999.

Table 4. *Cosmetic Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Year*

Year	Other Exposures	Potential Aspirations	Total
1993	20,806	348	21,154
1994	22,910	401	23,311
1995	23,522	367	23,889
1996	27,139	437	27,576
1997	27,380	396	27,776
1998	30,889	476	31,365
1999	30,819	469	31,288
Total	183,465	2,894	186,359

Source: American Association of Poison Control Centers TESS file.

Medical Outcome

Table 5 gives cosmetic *potential aspirations* and *other exposures* reported to TESS for children under 5 years old by *medical outcome*. Of 186,359 exposures, 836 resulted in a moderate medical outcome, 36 resulted in a major medical outcome, 1,060 were judged to be potentially toxic although they could not be followed up, and 1 resulted in death. Aspiration of a cosmetic hydrocarbon product classified in another TESS category [*hair care products, other (excluding peroxide)*] resulted in a second fatality discussed below in the section on fatalities.

Table 5. *Cosmetic Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Medical Outcome for 1993 through 1999*

Medical Outcome	Other Exposures	Potential Aspirations	Total
None	48,071	145	48,216
Minor	19,346	1,597	20,943
Moderate	752	84	836
Major	27	9	36
Death	0	1*	1*
No follow up-potentially toxic	1,015	45	1,060
No follow up-min possible effects	58,569	883	59,452
No follow up-nontoxic	53,395	92	53,487
Unrelated effect	2,290	38	2,328
Total	183,465	2,894	186,359

Source: American Association of Poison Control Centers TESS file.
*Aspiration of a cosmetic hydrocarbon product classified in another TESS category [*hair care products, other (excluding peroxide)*] resulted in a second fatality.

Potential Aspirations: Respiratory Effects

Table 6 gives the number of cosmetic *potential aspiration* cases reported to TESS for children under 5 years old by each of the 10 related respiratory effects defined in TESS [see Appendix A]. There were a total of 2,894 potential aspirations, 2,173 of which involved 1 or more related respiratory effects, and 721 of which involved no related respiratory effects. Note that the numbers in Table 6 exceed 2,894 due to some cases with multiple respiratory effects. Coughing/choking was the most frequently reported related respiratory effect with 2,129 cases. In addition, there were 47 cases of dyspnea, 14 cases of positive X-ray findings, 13 cases of bronchospasm, 11 cases of pneumonitis, 8 cases of respiratory depression, 7 cases of hyperventilation/tachypnea, and 4 cases of respiratory arrest.

Table 6 *Cosmetic Potential Aspirations Reported to TESS for Children under 5 Years Old by Respiratory Effect for 1993 through 1999*

Respiratory Effect(s)	Number
None	721
Bronchospasm	13
Cough/Choke	2,129
Cyanosis	0
Dyspnea	47
Hyperventilation/Tachypnea	7
Pneumonitis	11
Pulmonary Edema	0
Respiratory Arrest	4
Respiratory Depression	8
Positive X-Ray Findings	14

Source: American Association of Poison Control Centers TESS file.

Household Chemicals Exposures

Age

Table 7 gives household chemical *potential aspirations* and *other exposures* for children under 5 years old by *age*. There were 109,823 reported exposures from 1993 through 1999, 83.8% of which involved children under 3 years old.

Table 7. *Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Age for 1993 through 1999*

Age	Other Exposures	Potential Aspirations	Total	(%)
0-11 Months	8,544	676	9,220	(8.4)
1 Year	42,547	3,794	46,341	(42.2)
2 Years	34,034	2,481	36,515	(33.2)
3 Years	11,516	839	12,355	(11.2)
4 Years	4,961	431	5,392	(4.9)
Total	101,602	8,221	109,823	(100.0)

Source: American Association of Poison Control Centers TESS file.

Sex

Table 8 gives household chemical *potential aspirations* and *other exposures* for children under 5 years old by *sex*. Males were involved in both total exposures and potential aspirations more frequently than females.

Table 8. *Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Sex for 1993 through 1999*

Sex	Other Exposures	Potential Aspirations	Total	(%)
Male	59,655	5,062	64,717	(58.9)
Female	41,694	3,118	44,812	(40.8)
Unknown	253	41	294	(00.3)
Total	101,602	8,221	109,823	(100.0)

Source: American Association of Poison Control Centers TESS file.

Year

Table 9 gives household chemical *potential aspirations* and *other exposures* for children under 5 years old by *year* for 1993 through 1999.

Table 9. *Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Year*

Year	Other Exposures	Potential Aspirations	Total
1993	12,309	720	13,029
1994	14,280	830	15,110
1995	13,258	806	14,064
1996	17,036	1,769	18,805
1997	15,604	1,405	17,009
1998	13,808	808	14,616
1999	15,307	1,883	17,190
Total	101,602	8,221	109,823

Source: American Association of Poison Control Centers TESS file.

Medical Outcome

Table 10 gives household chemical *potential aspirations* and *other exposures* reported to TESS for children under 5 years old by *medical outcome*. Of 109,823 exposures, 1,427 resulted in a moderate medical outcome, 73 resulted in a major medical outcome, 2,018 were judged potentially toxic although they could not be followed up, and 2 resulted in death.

Table 10. *Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Medical Outcome for 1993 through 1999*

Medical Outcome	Other Exposures	Potential Aspirations	Total
None	45,044	650	45,694
Minor	12,247	4,584	16,831
Moderate	403	1,024	1,427
Major	9	64	73
Death	0	2	2
No follow up-potentially toxic	1,684	334	2,018
No follow up-min possible effects	23,091	1,116	24,207
No follow up-nontoxic	17,538	254	17,792
Unrelated effect	1,586	193	1,779
Total	101,602	8,221	109,823

Source: American Association of Poison Control Centers TESS file.

Potential Aspirations: Respiratory Effects

Table 11 gives the number of household chemical *potential aspiration* cases reported to TESS for children under 5 years old by each of the 10 related respiratory effects defined in TESS [see Appendix A]. There were a total of 8,221 potential aspirations, 6,113 of which involved 1 or more related respiratory effects, and 2,108 of which involved no related respiratory effects. Note that the numbers in Table 11 exceed 8,221 due to some cases with multiple respiratory effects. Coughing/choking was the most frequently reported related respiratory effect with 5,910 cases. In addition, there were 497 cases of positive X-ray findings, 355 cases of dyspnea, 207 cases of hyperventilation/tachypnea, 179 cases of pneumonitis, 67 cases of bronchospasm, 38 cases of cyanosis, 36 cases of respiratory depression, 8 cases of pulmonary edema, and 8 cases of respiratory arrest.

Table 11. *Household Chemical Potential Aspirations Reported to TESS for Children under 5 Years Old by Respiratory Effect for 1993 through 1999*

Respiratory Effect(s)	Number
None	2,108
Bronchospasm	67
Cough/Choke	5,910
Cyanosis	38
Dyspnea	355
Hyperventilation/Tachypnea	207
Pneumonitis	179
Pulmonary Edema	8
Respiratory Arrest	8
Respiratory Depression	36
Positive X-Ray Findings	497

Source: American Association of Poison Control Centers TESS file.

Combined Cosmetics and Household Chemicals Exposures

Age

Table 12 gives combined cosmetic and household chemical *potential aspirations* and *other exposures* for children under 5 years old by *age*. There were 296,182 reported exposures from 1993 through 1999, 86.7% of which involved children under 3 years old.

Table 12. *Combined Cosmetic and Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Age for 1993 through 1999*

Age	Other Exposures	Potential Aspirations	Total	(%)
0-11 Months	35,856	1,040	36,896	(12.5)
1 Year	124,526	5,178	129,704	(43.8)
2 Years	87,035	3,218	90,253	(30.5)
3 Years	26,842	1,123	27,965	(9.4)
4 Years	10,808	556	11,364	(3.8)
Total	285,067	11,115	296,182	(100.0)

Source: American Association of Poison Control Centers TESS file.

Sex

Table 13 gives combined cosmetic and household chemical *potential aspirations* and *other exposures* for children under 5 years old by *sex*. Males were involved in both total exposures and potential aspirations more frequently than females.

Table 13. *Combined Cosmetic and Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Sex for 1993 through 1999*

Sex	Other Exposures	Potential Aspirations	Total	(%)
Male	152,884	6,556	159,440	(53.8)
Female	131,525	4,514	136,039	(45.9)
Unknown	658	45	703	(0.2)
Total	285,067	11,115	296,182	(100.0)

Source: American Association of Poison Control Centers TESS file.

Year

Table 14 gives combined cosmetic and household chemical *potential aspirations* and *other exposures* for children under 5 years old by *year* for 1993 through 1999.

Table 14. *Combined Cosmetic and Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Year*

Year	Other Exposures	Potential Aspirations	Total
1993	33,115	1,068	34,183
1994	37,190	1,231	38,421
1995	36,780	1,173	37,953
1996	44,175	2,206	46,381
1997	42,984	1,801	44,785
1998	44,697	1,284	45,981
1999	46,126	2,352	48,478
Total	285,067	11,115	296,182

Source. American Association of Poison Control Centers TESS file.

Medical Outcome

Table 15 gives combined cosmetic and household chemical *potential aspirations* and *other exposures* reported to TESS for children under 5 years old by *medical outcome*. Of 296,182 exposures, 2,263 resulted in a moderate medical outcome, 109 resulted in a major medical outcome, 3,078 were judged potentially toxic although they could not be followed up, and 3 resulted in death. Aspiration of a cosmetic hydrocarbon product classified in another TESS category [*hair care products, other (excluding peroxide)*] resulted in a fourth fatality discussed below in the section on fatalities.

Table 15. *Combined Cosmetic and Household Chemical Potential Aspirations and Other Exposures Reported to TESS for Children under 5 Years Old by Medical Outcome for 1993 through 1999*

Medical Outcome	Other Exposures	Potential Aspirations	Total
None	93,115	795	93,910
Minor	31,593	6,181	37,774
Moderate	1,155	1,108	2,263
Major	36	73	109
Death	0	3*	3*
No follow up-potentially toxic	2,699	379	3,078
No follow up-min possible effects	81,660	1,999	83,659
No follow up-nontoxic	70,933	346	71,279
Unrelated effect	3,876	231	4,107
Total	285,067	11,115	296,182

Source: American Association of Poison Control Centers TESS file.
*Aspiration of a hydrocarbon product classified in another TESS category [*hair care products, other (excluding peroxide)*] resulted in a fourth aspiration-related fatality.

Potential Aspirations: Respiratory Effects

Table 16 gives the number of combined cosmetic and household chemical *potential aspiration* cases reported to TESS for children under 5 years old by each of the 10 related respiratory effects defined in TESS [see Appendix A]. There were a total of 11,115 potential aspirations, 8,286 of which involved 1 or more related respiratory effects, and 2,829 of which involved no related respiratory effects. Note that the numbers in Table 16 exceed 11,115 due to some cases with multiple respiratory effects. Coughing/choking was the most frequently reported related respiratory effect with 8,039 cases. In addition, there were 511 cases of positive X-ray findings, 402 cases of dyspnea, 214 cases of hyperventilation/tachypnea, 190 cases of pneumonitis, 80 cases of bronchospasm, 44 cases of respiratory depression, 38 cases of cyanosis, 12 cases of respiratory arrest, and 8 cases of pulmonary edema.

Table 16. *Combined Cosmetic and Household Chemical Potential Aspirations Reported to TESS for Children under 5 Years Old by Respiratory Effect for 1993 through 1999*

Respiratory Effect(s)	Number
None	2,829
Bronchospasm	80
Cough/Choke	8,039
Cyanosis	38
Dyspnea	402
Hyperventilation/Tachypnea	214
Pneumonitis	190
Pulmonary Edema	8
Respiratory Arrest	12
Respiratory Depression	44
Positive X-Ray Findings	511

Source: American Association of Poison Control Centers TESS file.

AAPCC TESS Fatality Data

As noted above, TESS recorded 3 fatalities involving aspiration of hydrocarbon products from 1993 through 1999 in the specified TESS categories for automotive and cosmetic products (077322, 077325, 077329, 077345, 013290, 039220, 039281, 039505, 039510, 039511, 077307, 077586, 191103, 191500, 254366, 254367). In addition, TESS recorded a fourth pediatric fatality associated with aspiration of a hydrocarbon product in a TESS category for hair care products (Other, 077326); this was the only fatality TESS recorded in this category from 1993 through 1999. The 4 fatalities recorded in TESS occurred in 1993, 1996, 1998, and 1999. The 1993 fatality involved ingestion and aspiration of a home-made cleaning compound possibly comprising detergents, alcohols, caustics, and hydrocarbons. According to the AAPCC TESS summary of this case, "Her chest roentgenogram revealed bilateral fluffy infiltrates secondary to hydrocarbon aspiration. Over the next 24 hours, the patient's status progressively deteriorated and she died despite aggressive supportive care." The 1996 fatality involved ingestion and aspiration of baby oil leading to pneumonitis This case was investigated by CPSC staff and is described further below. The 1998 fatality involved a 15-month old boy who ingested motor oil and died 51 days later. According to the AAPCC summary of this case, upon presentation to the emergency department 1 hour after the incident, "His oxygen saturation was 88% and his chest radiograph was normal." However, "Thirty-three hours after presentation, respiratory rate was 90 to 100 breaths/min and a repeat chest radiograph revealed right upper and right middle lobe infiltrates." The 1999 fatality involved a 12-month-old boy who ingested a large quantity of hair oil containing a blend of safflower, mineral, castor, avocado, sesame, and jojoba oils 40 minutes before arrival at an urgent care center. The patient exhibited persistent cough and hypoxemia, his respiratory status deteriorated, he developed bilateral pneumothoraces, and 7 days following exposure, he suffered multisystem organ failure and died.

CPSC INDP Fatality Data

A search of the CPSC in-depth investigations (INDP) file revealed 4 pediatic poisoning fatalities involving aspiration of hydrocarbon products from 1993 to date.

One of these fatalities occurred in 1993, after a 1-year old female ingested and aspirated an automotive cleaning compound. The victim was with her mother at the mother's boyfriend's home. While the mother and boyfriend were studying, they noticed the child with the cap from a bottle of automotive cleaning compound and blue fluid around the baby's mouth and on the floor. The victim's mother induced vomiting and called rescue officials, who transported the baby to the hospital. The child was transferred to another hospital, where she died. The medical examiner's report, included in the CPSC INDP file, lists the probable cause of death as (1) acute respiratory distress syndrome due to (2) sepsis due to (3) hydrocarbon aspiration.

A second fatality occurred in 1996, after a 1-year old male ingested and aspirated baby oil. The mother stated that she had just changed the baby's diaper and left a bottle of baby oil on a television next to the bed the baby was lying on. She left the room for a few minutes and upon returning found the baby on the floor in a puddle of baby oil. The baby was transported to a hospital and transferred to another hospital, where he died. The medical examiner's report listed the immediate cause of death as "complications of hydrocarbon (mineral oil) pneumonitis." This fatality was 1 of the 3 fatalities from 1993 through 1999 recorded in the TESS data described

above.

A third fatality occurred in early 1997, after a 12-month old female swallowed and aspirated baby oil in late 1996. According to the coroner's report included in the CPSC INDP file for this case, the infant's mother had removed the cap from a bottle of baby oil, filled the cap with baby oil, then left the open bottle of baby oil on a window sill by the baby's bed for several minutes while she went into another room. The mother then heard unusual sounds coming from the baby's room, returned to the room, and found the baby's face covered with baby oil and the bottle of baby oil on the bed. She called poison control and was told to give the baby copious amounts of liquid. The next day, when an ambulance came to the residence to pick up another person, the emergency medical technicians checked the child and advised the mother to take her to the hospital. The child and mother went to the hospital as passengers in the ambulance. At the hospital, the child was examined by an emergency room physician and released. The next day the baby was taken to a physician's office for examination and then admitted to the hospital. The child was subsequently transferred to another hospital, where she died According to the coroner's report, "The autopsy revealed that the decedent died as a result of a left hemothorax due to complications from swallowing/aspirating baby oil." This fatality was not reported in the previous CPSC report on hydrocarbons summarizing TESS baby oil poisoning data [8], because the case was never reported in the TESS database.

A fourth fatality investigated by CPSC staff occurred in 2000, after a 9-month old female ingested and aspirated a hair moisturizer product while in the care of her grandmother while the mother was at school. The victim was placed in the grandmother's bed for a nap and the grandmother intended to take a nap with the baby, but went downstairs to answer the telephone. Several minutes later, the victim's cousin informed the grandmother that the baby was vomiting and convulsing. The victim had apparently gone to a room across the hall and gotten the moisturizer from a sink or cabinet. Emergency medical services staff transported the victim to the hospital, where she was admitted and treated but died 6 days later. The hospital records indicate that an autopsy was to be done, but the coroner's report is not available at this time due to the recency of this fatality. The NEISS hospital record for the case indicates that the patient suffered respiratory failure and died in the intensive care unit.

Conclusion

This report documents a high incidence of pediatric exposure to cosmetics and household chemical product groups that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. Data sources include the U.S. Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) and In-Depth Investigations (INDP) files and the American Association of Poison Control Centers Toxic Exposure Surveillance System (TESS) file.

NEISS data for 1997 through 1999 yielded an estimated total number of pediatric exposures involving *household chemicals* of about 6,400. NEISS household chemical data are not directly comparable to TESS data, because NEISS product code categories do not correspond to TESS generic code categories. NEISS does not currently distinguish different cosmetic products, so cosmetic-related injuries reported to NEISS are not included in this report.

TESS data indicated that, from 1993 through 1999, there were 296,182 reported pediatric hydrocarbon exposures, with 186,359 related to *cosmetics*, and 109,823 related to *household chemicals*. During the same period, there were 11,115 reported *potential aspiration* exposures, with 2,894 related to *cosmetics*, and 8,221 related to *household chemicals*. Children under 3 years old were involved in 88.4% of *cosmetic* exposures and 83.8% of *household chemical* exposures. Males (females) were involved in 50.8% (48.9%) of *cosmetic* exposures and 58.9% (40.8%) of *household chemical* exposures. Gender was unknown in 0.2% of cases. Of the 11,115 potential aspirations in the combined *cosmetics* and *household chemicals* products, 1,108 resulted in a moderate medical outcome, 73 resulted in a major medical outcome, and 3 resulted in death. In addition, TESS recorded a fourth pediatric fatality associated with aspiration of a hydrocarbon product in a TESS category for hair care products (Other, 077326). In most cases, related respiratory effects were associated with potential aspiration of these hydrocarbon products. Coughing/choking was the most frequently reported related respiratory effect with 8,039 cases in the *cosmetic* and *household chemicals* categories defined above. In addition, there were 511 cases of positive X-ray findings, 402 cases of dyspnea, 214 cases of hyperventilation/tachypnea, 190 cases of pneumonitis, 80 cases of bronchospasm, 44 cases of respiratory depression, 38 cases of cyanosis, 12 cases of respiratory arrest, and 8 cases of pulmonary edema.

Detailed information about 7 separate fatality cases in AAPCC TESS and CPSC INDP files was discussed, 1 of which appeared in both AAPCC TESS and CPSC INDP files.

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Appendix A

Definitions of TESS *Exposure Routes*, *Medical Outcomes*, and *Respiratory Clinical Effects*

Exposure Routes

Ingestion: An exposure by the oral route. Exposures in which the material was put in the mouth but unlikely to have reached the stomach should be classified as ingestions. Ingestions accompanied by aspiration should be coded as aspirations. If aspiration is coded, ingestion will automatically be coded. It is not an error to code both ingestion and aspiration.

Inhalation/nasal: An exposure by the pulmonary route (tracheal or nasal). This route usually pertains to gaseous or vaporized agents.

Aspiration: An exposure by the pulmonary route (tracheal). This route usually pertains to liquid or solid agents and occurs during or following an ingestion. If aspiration is coded, ingestion will automatically be coded by the scanner or your on-line system. It is not an error to code both ingestion and aspiration.

Ocular: An exposure involving the eyeball.

Dermal: An exposure involving the skin, hair, or fingernails.

Bite/sting: An exposure resulting from an animal bite or sting with or without envenomation

Parenteral: An exposure resulting from the injection of a substance into the body.

Other: Any other route of exposure not listed above.

Unknown: The route of exposure is unknown.

Note: At least one route must be selected. Multiple routes may be selected.

Medical Outcomes

No Effect: The patient developed no signs or symptoms as a result of the exposure.

Minor Effect: The patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved rapidly without residual disability or disfigurement.

Moderate Effect: The patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms. Symptoms were not life-threatening, and the patient has no residual disability. Usually some form of treatment is indicated.

Major Effect: The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement, e.g., repeated seizures or status epilepticus, respiratory compromise requiring intubation, ventricular tachycardia with hypotension.

Death: Only those deaths which are probably or undoubtedly related to the exposure are coded here.

Unrelated Effect: The exposure was probably not responsible for the clinical effect.

No Follow Up: Either the patient could not be followed in spite of a potentially significant exposure or follow-up calls were limited because the substance implicated was nontoxic, the amount was insignificant, or the exposure was likely to result in only minimal toxicity.

Respiratory Clinical Effects

Bronchospasm: Narrowing of bronchi by muscular contraction in response to some stimulus; wheezing; reactive airway diseases.

Cough/Choke: A form of violent exhalation by which irritant particles in the airways can be expelled; interruption of respiration by obstruction.

Cyanosis: Bluish discoloration of the skin and mucuous membranes.

Dyspnea: Labored or difficult breathing; shortness of breath.

Hyperventilation/Tachypnea: Breathing at an abnormally rapid rate at rest; diagnosis is usually made with an arterial blood gas.

Pneumonitis: Inflammation of the pulmonary parenchyma.

Pulmonary edema: Accumulation of fluid in the lungs. Include cardiogenic and noncardiogenic etiologies.

Respiratory arrest: Cessation of spontaneous respirations.

Respiratory depression: Diminshed tidal volume and/or rate. Inadequate ventilation. Use this code only if objective information is provided to support the diagnosis of respiratory depression.

X-ray findings (+): Pulmonary X-ray findings other than normal.

TAB C

DRAFT

Billing Code 6355-01P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR PART 1700

Household Products Containing Hydrocarbons; Notice of Data Availability and Request for Comments

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of data availability and request for comment.

SUMMARY: In the Federal Register of January 3, 2000, the Consumer Product Safety Commission ("CPSC" or "Commission") published a notice of proposed rulemaking ("NPR") proposing child-resistant packaging requirements for household chemical and cosmetic products with viscosity less than 100 Saybolt Universal Seconds ("SUS") containing 10 percent or more hydrocarbons. 65 FR 93. Since that time, CPSC's staff has acquired brand name-specific data on exposure to possible hydrocarbon-containing cosmetics and has conducted an analysis of that data as well as an additional analysis of the data available when the NPR was issued.

This notice makes these staff analyses available for public comment. Today's notice does not re-open the comment period on the NPR.

DATES: The Commission must receive any comments in response to this notice by **[insert date that is 30 days after publication].**

ADDRESSES: Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety

Commission, Washington, D.C. 20207-0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504-0800. Comments also may be filed by facsimile to (301)504-0127 or by e-mail to cpsc-os@cpsc.gov. Comments should be captioned "Notice of Additional Hydrocarbon Data."

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0477, ext. 1196.

SUPPLEMENTARY INFORMATION:

A. BACKGROUND

The January 3, 2000 NPR presented ingestion data collected by the American Association of Poison Control Centers' ("AAPCC") Toxic Exposure Surveillance System ("TESS") for general cosmetic categories that may contain low viscosity hydrocarbons. The categories included: 1) miscellaneous nail products; 2) sunscreen and suntan preparations; 3) bubble bath and bath oil; and 4)creams, lotions, and make-up. The data presented in the NPR were from the years 1995 through 1997.

A total of 74,042 ingestion incidents were reported in these product categories. While these incidents were not limited to known hydrocarbon-containing cosmetics, they demonstrate that children access the contents of these types of products in the home. Thus, if such products contain hydrocarbons of low viscosity, aspiration and therefore serious injury, can result. In addition, the NPR included 1996-1997 AAPCC data for exposures

to baby oil, a cosmetic product known to contain low viscosity mineral oil, which is a hydrocarbon.

An analysis of brand name-specific cosmetic data obtained by CPSC staff after the NPR was issued is presented below. Data on additional deaths and the additional CPSC staff analysis of the data available when the NPR was issued are also presented.

B. BRAND-SPECIFIC COSMETIC DATA

At the December 3, 1999 Commission briefing on the NPR, Commissioner Gall requested that the staff develop a plan for the collection and analysis of additional data related to ingestion incidents involving mineral oil-based cosmetics.[1] The staff recommended, and the Commission approved, the purchase of additional information from the AAPCC on ingestion incidents involving mineral oil-based cosmetics. Permission was obtained from the AAPCC Board of Directors to purchase brand name data for the year 1998 for four cosmetic categories. Data on the following product categories were purchased: 1) miscellaneous nail products; 2) sunscreen and suntan preparations; 3) bubble bath and bath oil; and 4) creams, lotions, and make-up.

A comment was received from the Cosmetic, Toiletry, and Fragrance Association (CTFA) (CP00-1-6) in response to the NPR requesting the opportunity to review and comment on the additional cosmetic data purchased from the AAPCC. These data

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[1] *See* Statement of Commissioner Mary Sheila Gall on publication of a notice of proposed rulemaking to require special packaging for low-viscosity hydrocarbons, December 3, 1999. *See also*, Statement of Commissioner Thomas H. Moore on the same subject. (Copies of these statements are available from the CPSC Office of the Secretary.)

contain brand names and must remain proprietary under the terms by which CPSC acquired them from the AAPCC. Therefore the database cannot be made available to the public. However, the staff analysis of the data that is summarized in this notice is available to the public. Copies of may be obtained from the Office of the Secretary. The analysis is also available on the CPSC world wide web site at www.cpsc.gov/***[insert full URL before transmitting notice to the Federal Register]***

The supplemental AAPCC cosmetic database purchase contained a total of 31,903 ingestion cases coded as: 1) miscellaneous nail products; 2) sunscreen and suntan preparations; 3) bubble bath or bath oil; and 4) creams, lotions, and make-up. Of these, 538 cases involved ingestion of more than one substance and were therefore eliminated from consideration. Of the 31,365 single substance ingestions, 476 involved potential aspirations as defined below by CPSC staff in Section D., *Additional Analysis of Data Available when NPR Was Issued.* Seventeen of the aspiration cases involved a serious medical outcome.[2]

CPSC staff eliminated 2,049 products (22,262 exposures) from further consideration because either the products were known not to contain hydrocarbons or the formulations were emulsions or solids. Of the remainder, 30 products (1,461 exposures) would require child-resistant packaging under the proposed rule. Staff

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[2] "Serious medical outcome" is defined for purposes of this analysis as a TESS case with an outcome coded as "moderate effect," "major effect," death, or "not followed up-potentially toxic."

lacked sufficient information to make that determination for 222 products (7,642 exposures). Some of these were from a specific cosmetic product category such as "bath oil," some members of which may require packaging under the rule as proposed, but were products for which a brand name was not available. The remaining ones were products for which no formulation information was available.

The staff evaluated the combined data set of cases that were either known to be or might be subject to the rule as proposed. The two parameters evaluated were potential aspiration and serious injury. Five potential aspiration cases were identified in this manner as having serious medical outcomes. Three of these cases involved baby oil and two involved bath oil. There were 224 additional cases coded as potential aspirations that did not result in serious effects. Seventy-nine cases resulted in serious outcomes but did not meet the staff criteria for potential aspiration.

C. ADDITIONAL DEATHS

Seven fatalities were identified in categories of products known to contain hydrocarbons. Five of these deaths were not reported in the NPR or the preceding advance notice of proposed rulemaking ("ANPR"). 62 Fed. Reg. 8,659 (February 26, 1997). Of these, three deaths were identified in TESS that were caused by products that appear not to be subject to the rule. The first case was the death of a child following ingestion and aspiration of a homemade cleaning product. The second case was the death of

a child following ingestion and aspiration of motor oil. The third TESS case was the death of a child following ingestion and aspiration of hair oil. The products involved in these three deaths either contain less than 10 percent hydrocarbons or have a viscosity greater than 100 SUS at 100° F.

The other two deaths that were identified in CPSC databases were apparently caused by products that would be subject to the rule as proposed. The first death occurred in 1997 when a 12-month female died 45 days following ingestion of baby oil. The autopsy revealed that the child died as a result of a left hemothorax due to complications from swallowing and aspirating baby oil.

The second death occurred in 2000 when a 9-month old female died six days following the ingestion of a hair moisturizer product. The patient suffered respiratory arrest and died in the intensive care unit.

D. ADDITIONAL ANALYSIS OF DATA AVAILABLE WHEN NPR WAS ISSUED

Commissioner Gall's specific interest in cases involving mineral oil-based cosmetics also prompted a reevaluation by CPSC staff of the data available at the NPR stage with a focus on aspiration. The data presented in the NPR contained 114 cases of cosmetic exposure coded as aspirations by the AAPCC for the years 1995, 1996, and 1997 (29, 36, and 49 respectively).

TESS codes identify the routes of exposure for poisoning cases. These route codes include, "ingestion," "aspiration," "inhalation/nasal," "ocular," "dermal," "bite/sting," or

"parenteral." The 74,042 incidents identified in the NPR were ingestions that did not also involve other routes of exposure. However, according to AAPCC coding guidelines, all cases coded as aspiration are also coded as ingestions.

Upon reevaluation, the CPSC staff believed that using only incidents coded with the aspiration route of exposure was underestimating the number of aspiration incidents. Numerous cases not coded as aspirations resulted in respiratory effects. Therefore, in addition to any case coded as an aspiration by the AAPCC, any inhalation or nasal route of exposure case, and any ingestion case that also had related respiratory effects, was considered by the CPSC staff to be a potential aspiration. Many of these cases are not coded as aspiration cases by the AAPCC. For example, a case of aspiration of hydrocarbon following vomiting may not be coded as an aspiration by the AAPCC because the initial route of exposure may have been ingestion. However, if the child exhibits respiratory effects related to the poisoning, the case would be considered an "aspiration" for purposes of this analysis.

The CPSC staff reanalyzed the TESS data originally presented in the NPR to take into account the additional cases of potential aspiration. In addition, several other changes were made. The analysis was expanded to include cases involving all routes of exposure. However, cases involving more than one product and cases where the age of the child was unknown were eliminated.

Reanalysis of the TESS cosmetic data in this manner resulted in 1200 cases of potential aspiration for the years 1995-1997 as opposed to the 114 cases identified in the NPR.

The TESS cosmetic data for the years 1993 through 1999 show 186,359 exposures with 2,894 potential aspirations. The TESS data also show 109,823 exposures to household chemical product categories that may contain hydrocarbons, 8,221 of which were potential aspirations.

The detailed staff reanalysis of these data is available to the public. Copies may be obtained from the Office of the Secretary. The reanalysis is also available on the CPSC world wide web site at www.cpsc.gov/***[insert full URL before transmitting notice to the Federal Register]***

Dated: _____

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Sadye E. Dunn, Secretary,
Consumer Product Safety Commission